UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,354	12/12/2001	William Dall'Acqua	10271-027	2678

20583 7590 12/29/2003

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,354	DALL'ACQUA ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-86 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-86 are pending.

Restriction Requirement

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 4 , 7 –20 , 58 , 69 and 86 drawn to a modified IgG, , a pharmaceutical composition and a kit comprising modified IgG, wherein modification is an amino acid substitution, classified in Class 530, subclasses 387.1, 387.7 and 387.9, Class 424, subclass 130.1; Class 435, subclass 810.

II. Claims 5 ,7 , 8 , 20, 58 ,69 and 86 drawn to a modified IgG, , a pharmaceutical composition and a kit comprising modified IgG,wherein modification is an amino acid deletion, classified in Class 530, subclasses 387.1, 387.7 and 387.9; Class 424, subclass 130.1; Class 435, subclass 810. .

III. Claims 6 ,7 , 8 , 20 ,58 , 69 and 86 drawn to a modified IgG, a pharmaceutical composition and a kit comprising modified IgG,, wherein modification is an amino acid insertion, classified in Class 530, subclasses 387.1, 387.7 and 387.9; Class 424, subclass 130.1; Class 435, subclass 810.

IV . Claims 24 , 27 –39 , 59 and 70 drawn to a fusion protein, comprising a non-IgG polypeptide, a pharmaceutical composition and a kit comprising said fusion protein wherein modification is an amino acid substitution, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 134.1; Class 435, subclass 810.

V. Claims, 25 , 27 –29, 59 and 70 drawn to a fusion protein, comprising a non-IgG polypeptide, a pharmaceutical composition and a kit comprising said fusion protein, wherein modification is an amino acid deletion, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 134.1; Class 435, subclass 810.

VI. Claims 26 –29, 59 and 70 drawn to a fusion protein, comprising a non-IgG polypeptide, a pharmaceutical composition and a kit comprising said fusion protein wherein modification is an amino acid insertion, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 134.1; Class 435, subclass 810.

VII . Claims 43 , 46-57, 60 and 71 drawn to a molecule , comprising a modified IgG constant domain, a pharmaceutical composition and a kit comprising said molecule, wherein modification is an amino acid substitution, classified in Class 530, subclasses 350 and 387.1, Class 424, subclass 133.1; Class 435, subclass 810.

VIII . Claims, 44 , 60 and 71 drawn to a molecule , comprising a modified IgG constant domain, a pharmaceutical composition and a kit comprising said molecule wherein modification is an amino acid deletion, classified in Class 530, subclasses 350 and 387.1; class 424, subclass 133.1; Class 435, subclass 810.

IX . Claims, 45 , 60 and 71 drawn to a molecule , comprising a modified IgG constant domain, a pharmaceutical composition and a kit comprising said molecule, wherein modification is an amino acid insertion, classified in Class 530, subclasses 350 and 387.1; Class 424, subclass 133.1; Class 435, subclass 810.

X. Claims 61-62 , 72-77, 79-84 drawn to a method of treating or preventing a disease or disorder, and a method of vaccinating a subject comprising administering to a patient in need modified human or humanized IgG, classified in Class 530, subclasses 387.1, 387.3, Class 424, subclass 130.1.

XI. Claims 63 and 78 drawn to a method of treating a disease or disorder and a method of vaccinating a subject , comprising administering to a patient in need a fusion protein comprising a non-IgG polypeptide, classified in Class 530, subclasses 387.1, 387.3, Class 424, subclasses 130.1 and 192.1.

XII. Claim 64 drawn to a method of treating a disease or disorder, comprising administering to a patient in need a molecule comprising a modified IgG constant domain , classified in Class 530, subclasses 387.1, 387.3, Class 424, subclasses 130.1 and 192.1.

XIII. Claims 65 and 67, drawn to a nucleic acid comprising a nucleotide sequence encoding the modified IgG constant domain and a host cell comprising said nucleic acid, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 325.

XIV. Claims 66 and 68, drawn to a nucleic acid comprising a nucleotide sequence encoding the fusion protein comprising a non-IgG polypeptide and a host cell comprising said nucleic acid, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 325.

XV. Claim 85 drawn to a method of in vivo diagnosis in a subject, comprising administrating to a subject an effective amount of the modified human or humanized IgG classified in Class 530, subclasses 387.1, 387.3, Class 424, subclass 130.1.

Claim 1-3 links inventions of Groups I, II and III; Claim 21-23 links inventions of Groups IV, V and VI; Claim 40-42 links inventions of Groups VII, VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3; 21-23 and 40-42. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Groups I-IX , XIII and XIV are different products. Modified IgG, fusing proteins, nucleic acids and host cells differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct.

4. Groups X-XII and XV are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

6. In addition, each group reads on and or uses patentable distinct sequences, for example, as recited in claims 12 –14, 20 and 76. Each sequence is patentably distinct because they are unrelated sequences and further restriction is applied to each group. For each elected group drawn to or using amino acid, the Applicant must further elect a single amino acid sequence drawn to or using nucleotide sequence, the Applicant are required to elect a single sequence (See MPEP 803.04).
In view of limited office resources , only a single nucleic or amino acid sequence will be examined in this application. In addition, to the specific selected sequence, those sequences which are patentably indistinct from the selected sequences will be also examined.

Examination will be restricted to only the elected sequences.

Species Election

7. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

8. If one of Groups I-IX , XIII or XIV is elected, applicant is required to elect one specific position of modification, as recited for example in claims 1-3, 9-10, and one specific substitution of the amino acid, as recited for example in claims 11 and 15.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

9. If one of the groups X-XII or XV is elected , Applicant is required to elect a specific method of treating or preventing a disease or specific method of in vivo diagnosis in a subject, wherein human or humanized IgG is modified at one specific position, as recited for example in claim 3 and one specific substitution of the amino acid, as recited for example in claims 11.

These species are distinct because a specific method of treating or preventing a disease or specific method of in vivo diagnosis in a subject, wherein human or humanized IgG is modified at one specific position, as recited for example in claim 3 and one specific substitution of the amino acid, as recited for example in claims 11 differ with respect to ingredients and method. Furthermore, the examination of specific human or humanized IgG in the methods of treating or preventing a disease or specific method of in vivo diagnosis in a subject, would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the

election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

A telephone call was made to Anthony Insoga on 12/05/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
December 22, 2003

Christina Chan
CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600